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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,743	10/05/2001	John A Flygare	018781-001823US	5345
22907	7590	03/31/2006		
BANNER & WITCOFF 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001			EXAMINER RAO, DEEPAK R	
			ART UNIT 1624	PAPER NUMBER

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/972,743

Applicant(s)

FLYGARE ET AL.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 January 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 11, 18, 41, 43, 44, 58-62, 95, 96, 98-109 and 111 ☒ are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 1-3, 11, 18, 41, 61, 62, 95, 98, 100-102, 108, 109 and 111 ☒ are allowed.  
6) ☒ Claim(s) 43, 44, 58-60, 96, 103, 106 and 107 ☒ are rejected.  
7) ☒ Claim(s) 99, 104-105 ☒ are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This office action is in response to the amendment filed on January 4, 2006.

Claims 1-3, 11, 18, 41, 43-44, 58-62, 95-96, 98-109 and 111 are pending in this application.

#### ***Withdrawn Rejections/Objections:***

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The terminal disclaimer filed on January 4, 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 6,121,304 has been reviewed and is accepted. The terminal disclaimer has been recorded. In view of the terminal disclaimer, the obviousness-type double patenting rejection over US'304 is hereby withdrawn.

#### ***The following rejections are maintained:***

1. Claims 106-107 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a disease characterized by high low density lipoprotein particles or cholesterol levels in the blood selected from atherosclerosis, pancreatitis, and hyperlipoproteinemia, does not reasonably provide enablement for a method of reducing the level of low density lipoprotein particles or cholesterol levels in the blood of a mammalian subject generally. The specification does not enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The reasons provided in the previous office action are incorporated here by reference.

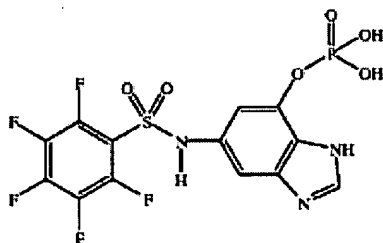
Applicant's arguments have been fully considered but they were not found to be persuasive with respect to the above claims. Applicant submits that the claim is limited to the specific disease states that are fully enabled. The instant claims however, are drawn to 'a method of reducing the level of low density lipoprotein particles or cholesterol in the blood of a mammalian subject in need thereof', without specifically identifying a disease state or condition and therefore include any or all types of disease states that are associated with the recited mechanism. The instant claims appear to be 'reach through' claims. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification thereby requiring undue experimentation for one of skill in the art to practice the invention.

2. Claims 43-44, 58-60, 96, 103 and 106-107 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 10-15, 16-18, 25-30 and 31-32 of U.S. Patent No. 6,417,176. The reasons provided in the previous office action are incorporated here by reference.

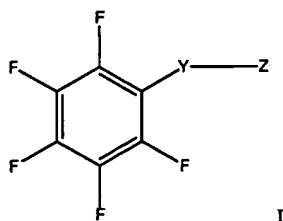
Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the reference claims are directed to certain arylsulfonamide phosphate derivatives' and that 'there is no analogous structure in the reference compounds'.

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However, contrary to applicant's argument, the reference claims are also drawn to a therapeutic method administering a compound of formula (shown in claim 1 of the reference) wherein Ar is a pentafluorophenyl (see claim 3); and  $R^2$  and  $R^3$  attached to adjacent carbon atoms, together form a fused 5-7 membered ring. The reference further discloses a specific compound (see col. 12, lines 44-53) wherein the phenyl group taken with  $R^2$  and  $R^3$  together represents a benzimidazolyl group which is a heteroaryl group (see the structural formula of reference compound depicted below for convenience):



The instant method claims recite a structural formula:



wherein Y can be SO<sub>2</sub> and Z is NR<sup>1</sup>R<sup>2</sup> wherein R<sup>2</sup> is optionally substituted heteroaryl. The instant claims therefore, include compounds wherein R<sup>2</sup> is heteroaryl having any type of substituent (since none is expressly provided in the claims) and as shown above, the reference claims include compounds wherein a substituted heteroaryl is directly attached to the sulfonamide nitrogen. Therefore, the instant claims overlap the reference claims.

***Allowable Subject Matter***

Claims 1-3, 11, 18, 41, 61-62, 95, 98, 100-102, 108-109 and 111 are allowed. Claims 99, 104 and 105 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

March 30, 2006